

REMARKS

Claims 228-235 and 244-281 are pending in this application. By this Amendment claims 276-281 are added. The added claims introduce no new matter. A Request for Continued Examination is attached. Reconsideration of the application based on the above amendments and the following remarks is respectfully requested.

The Office Action, in paragraph 5, rejects claims 228, 230-233, 235 and 272-275 under 35 U.S.C. §103(a) as being unpatentable over EP 0 376 763 to McKelvey et al. (hereinafter "McKelvey"). The Office Action, in paragraph 6, rejects claims 229 and 234 under 35 U.S.C. §103(a) as being unpatentable over McKelvey in view of WO 96/29865 to Fahy et al. (hereinafter "Fahy II"). The Office Action, in paragraph 7, rejects claims 244, 246-253, 255, 256, 258-263 and 265 under 35 U.S.C. §103(a) as being unpatentable over McKelvey in view of U.S. Patent No. 5,586,438 to Fahy and U.S. Patent No. 6,238,908 to Armstrong (hereinafter "Armstrong"). The Office Action, in paragraph 8, rejects claims 248 and 257 under 35 U.S.C. §103(a) as being unpatentable over McKelvey in view of Fahy, Armstrong and Fahy II. The Office Action, in paragraph 9, rejects claims 254 and 271 under 35 U.S.C. §103(a) as being unpatentable over McKelvey in view of Fahy, Armstrong and U.S. Patent No. 5,451,524 to Coble et al. (hereinafter "Coble"). The Office Action, in paragraph 10, rejects claims 264 and 266-270 under 35 U.S.C. §103(a) as being unpatentable over McKelvey in view of Fahy, Armstrong and U.S. Patent No. 6,300,875 to Schafer. These rejections are respectfully traversed.

The Office Action, in paragraph 5, concedes that McKelvey does not teach the organ perfusion apparatus and the transporter are separate units, as positively recited in claims 228 and 233. To cure this deficiency, the Office Action asserts that it would have been obvious to one of ordinary skill in the art to modify McKelvey in the manner suggested by the Office

Action to render obvious the combinations of all of the features recited in claims 228 and 233. The analysis of the Office Action fails for at least the following reasons.

The Office Action, in paragraph 5, asserts that McKelvey teaches a portable housing that can be inserted into a base unit and that can be transported independently of the base unit. The Office Action asserts that it would have been obvious to one of ordinary skill in the art to provide both a separate base unit and a separate transportation unit for the portable housing. This assertion, however, is not supported by the disclosure of McKelvey.

McKelvey teaches a device for transporting an organ for transplantation (Abstract). With reference to Fig. 3, McKelvey teaches a cabinet 30 and removable organ unit 31, which includes the housing 10 for receiving the organ, the venous reservoir 11, the blood pump 12, the heat exchanger 13, the oxygenator 14, the blood filter 15, the blood flow meter 16, the sensor probes 17, the pressure monitor 18, the temperature probe 25, the sampling conduit 23, the blood exchange pump 27, and reservoirs 28 and 29 (col. 5, lines 18-42). McKelvey further teaches that the removable organ unit 31 allows an organ to be harvested in the sterile field of an operation room, housed within the sterile organ reservoir 10 and placed into the removable organ unit 31 (col. 6, lines 5-9). With reference to Fig. 5, McKelvey further discloses the structure of organ reservoir 10, i.e., that organ reservoir 10 is fitted with a lid 32 and various tubes fitted to the reservoir (col. 6, line 42 - col. 7, line 38). Based on this disclosure, and apparently this disclosure alone, the Office Action asserts that the combination of the specifically recited features in claims 228 and 233 would have been obvious. However, the Office Action fails to establish a *prima facie* case of obviousness.

MPEP §2143.03 states "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *See also In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). This standard is not met here at least because the Office Action fails to establish how the above-quoted feature is even suggested by

McKelvey. For example, there is no suggestion in McKelvey to provide a separate base unit and a separate transportation unit for the portable housing in light of McKelvey's disclosure that only a portable housing and a base unit are desired to solve the problems to which McKelvey is directed.

Further, the Office Action's conclusory statement regarding the modification of McKelvey simply "in view of the disclosure" does not meet the articulated standard required to demonstrate obviousness. The Federal Circuit recently reaffirmed its prior holdings asserting that "rejections on obviousness grounds cannot be sustained by mere conclusory statement; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006). See also the Supreme Court's reasoning in *KSR v. Teleflex*, requiring explicit "articulated reasoning with a rational underpinning" to support a legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350, slip op. at 14 (2007), citing *In re Khan* 441 F.3d 997, 998 (Fed. Cir. 2006). This standard is not met here as no articulated reasoning with some rational underpinning is provided in order to meet the standard of obviousness required by the judicial precedent for modifying references in alleging obviousness. In particular, the Office Action's asserted motivation in view of the McKelvey disclosure does not (1) provide any objective evidence of motivation, or (2) rationally relate to the alleged modification of McKelvey. In other words, there is no rational basis for concluding that one of ordinary skill in the art would have been motivated to modify McKelvey to include a transporter with all of the variously recited features in claims 228 and 233. For example, McKelvey's disclosure that the portable housing could be "transportable" would have, likely, deterred one of ordinary skill in the art from seeking an additional transporter in which to house the portable housing itself to form a separate organ perfusion apparatus and transporter, as recited in the pending claims.

Additionally, MPEP §2143.01 instructs that "[t]he mere fact that references can be combined or modified does not render the resulting combination obvious unless the prior art also suggests the desirability of the combination." MPEP §2143.01 further instructs that "[a]lthough a prior art device 'may be capable of being modified to run the way the apparatus is claimed, there must be some suggestion or motivation in the reference to do so.'" *See In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Applicants respectfully submit that the rejection of at least pending claims 228 and 233 is improper in view of at least MPEP §2143.01 because the Office Action lacks the required showing to support the conclusion that one of ordinary skill in the art would have been motivated to modify McKelvey in the manner suggested by the Office Action.

At least for the reasons discussed above, to conclude that, when confronted with the problem disclosed in the background portion of Applicants' disclosure, one might have turned to McKelvey to address that problem, is a conclusion that can only be arrived at through improper application of hindsight reasoning based on the roadmap provided by Applicants' disclosure.

Fahy, Fahy II, Armstrong, Coble and Schafer are not applied in a manner to overcome the above-identified shortfalls in the application of McKelvey to the subject matter of the pending claims.

For at least the foregoing reasons, the applied references cannot reasonably be considered to teach, or to have suggested, the combinations of all of the features positively recited in independent claims 228 and 233. Additionally, claims 229-232, 234, 235, 244-271 are also neither taught, nor would they have been suggested, by the applied references for at least the respective dependence of these claims, directly or indirectly, on an allowable base claim, as well as for the separately patentable subject matter that each of these claims recites.

Accordingly, reconsideration and withdrawal of the rejections of claims 228-235 and 244-275 under 35 U.S.C. §103(a) as being unpatentable over any combination of the applied references, are respectively requested.

Additionally, the applied references, individually or in combination, do not teach, nor can they reasonably be considered to have suggested, an organ fitting, wherein the organ fitting is configured (1) to at least one of adapt to or hold the organ independently from any of the organ perfusion apparatus, the transporter or the portable housing, and (2) to be received by the portable housing, as recited in claims 276 and 278, tubing configured to perfuse the organ and adjustably connect to the organ fitting and the portable housing, as recited in claims 277 and 279, and the transporter is interfaced to a computer network, as recited in claims 280 and 281. Support for the subject matter recited in these claims can be found in at least pages 16-19 of Applicants' specification.

In view of the foregoing, Applicants respectfully submit that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 228-235 and 244-281 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned representative at the telephone number set forth below.

Respectfully submitted,



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Attachments:

Request for Continued Examination
Petition for Extension of Time

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